

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA

vs.

CRIMINAL ACTION
No. 10-10355-JLT-1

SB PHARMCO PUERTO RICO,
INC.

* * * * *

BEFORE THE HONORABLE JOSEPH L. TAURO
UNITED STATES DISTRICT JUDGE
WAIVER, PLEA AND SENTENCING HEARING

A P P E A R A N C E S

OFFICE OF THE UNITED STATES ATTORNEY
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Boston, Massachusetts 02210
for the United States
By: Susan G. Winkler, AUSA
Shannon T. Kelley, AUSA
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for the defendant
By: Geoffrey E. Hobart, Esq.
Matthew J. O'Connor, Esq.

Courtroom No. 22
John J. Moakley Courthouse
1 Courthouse Way
Boston, Massachusetts 02210
November 8, 2010
2:20 p.m.

CAROL LYNN SCOTT, CSR, RMR
Official Court Reporter
One Courthouse Way, Suite 7204
Boston, Massachusetts 02210
(617) 330-1377

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I N D E X

E X H I B I T S

COURT:

FOR ID.

No. 1	Trustee Authorization	3
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P R O C E E D I N G S

THE CLERK: All rise for the Honorable Court.

THE COURT: Good afternoon, everybody.

THE CLERK: This is criminal matter No. 10-10355,
United States of America versus SB Pharmco Puerto Rico, Inc.

Counsel please identify themselves for the record.

MS. WINKLER: Susan Winkler for the government
along with Shannon Kelley, a U.S. Assistant Attorney, and
Mark Josephs with the Office of Consumer Lit. at the
Department of Justice.

THE COURT: Okay. Nice to see you.

MR. HOBART: Geoffrey Hobart and Matthew O'Connor
for the defendant, Your Honor.

THE COURT: Okay. Sit down, everybody.

I have the trustee authorization for Mr. Hobart to
represent the corporation in this proceeding.

MR. HOBART: That's correct, Your Honor.

THE COURT: All right. We will mark this Court
Exhibit 1 for the purpose of this occasion.

(Court Exhibit No. 1 received in evidence.)

THE COURT: Mr. Hobart, I am talking to you now in
your representative capacity. I have two matters before me.
One is the waiver of indictment and the plea to an
information.

Dealing first with the waiver of indictment, I am

1 going to go over a number of matters that I know are
2 familiar to you but nonetheless need to be said. You
3 represent the company and have been given authority to plead
4 its case before me this afternoon.

5 And I am going to remind you of the obvious and
6 that is that the charges that are pending against your
7 client, against you representing your client as well, the
8 charges are felonies. They are serious crimes and,
9 therefore, they permit you to require the government to
10 first proceed against you and against the company by way of
11 grand jury presentment and require the government to
12 convince the grand jury by a majority vote, at least 12 to
13 11, that there is probable cause to believe that certain
14 criminal activity which is the subject of this proceeding
15 today was committed by your client.

16 Do you understand that?

17 **MR. HOBART:** I do, Your Honor.

18 **THE COURT:** And without laboring the point, I want
19 to make sure that you understand that the grand jury
20 process, although superficially is an accusatory one, it is
21 a very valuable one in terms of shielding innocent people
22 and companies and all from unwarranted accusation.

23 And so I want you to appreciate that it may be that
24 after presentment of evidence to the grand jury the grand
25 jury would decide that there was not probable cause to

1 believe that the criminal activity involving your client
2 should go forward and that there would be a no plea and the
3 result of that, at least for the time being, would be that
4 nothing would happen and the case would be, at least
5 temporarily, over.

6 Do you understand that?

7 **MR. HOBART:** I do, Your Honor.

8 **THE COURT:** The other side of that is as long as
9 you understand that you have this constitutional right to
10 require the government to proceed against you by way of
11 indictment and you are satisfied with the information that
12 has been presented to you and that you feel that you are
13 capable of making a knowing waiver of that right, you have
14 the right, like anything else, to give up the right. And so
15 I am asking you is it your intention to waive indictment
16 here today?

17 **MR. HOBART:** It is, Your Honor.

18 **THE COURT:** All right. I will approve the waiver.

19 Now, you are going to plead guilty to Count 1,
20 interstate shipment of adulterated drugs.

21 Do you understand that?

22 **MR. HOBART:** Yes.

23 **THE COURT:** And the penalties that you face if you
24 do this you -- when I say "you," I mean your company and
25 you -- you face the following maximum penalties on Count 1

1 of the information. And you tell me if this is not your
2 understanding:

3 A fine of \$500,000 or twice the gross gain derived
4 from the offense or twice the gross loss to a person other
5 than the defendant, whichever is greatest, and given SB
6 Pharmco's gross gain from the sales of Paxil CR, Avandamet,
7 Kytril and Bactroban that were deemed adulterated between
8 March 2003 and October 2004, they total \$98,834,224, the
9 maximum possible fine in connection with this count is
10 \$197,668,448.

11 Do you understand that?

12 **MR. HOBART:** We do, Your Honor, and I agree that
13 that is the maximum fine.

14 **THE COURT:** You agree with that number?

15 **MR. HOBART:** Yes.

16 **THE COURT:** All right. And a term -- going down
17 the -- continuing with the penalties that your client faces,
18 a term of probation of not more than five years.

19 Do you understand that?

20 **MR. HOBART:** Yes, Your Honor.

21 **THE COURT:** Restitution to any victims of the
22 offense; do you understand that?

23 **MR. HOBART:** Yes.

24 **THE COURT:** A mandatory special assessment of \$400;
25 do you understand that?

1 **MR. HOBART:** Yes.

2 **THE COURT:** And my understanding is that the United
3 States and SB Pharmco agree pursuant to Federal Criminal
4 Procedure that the appropriate disposition in this case is
5 as follows, and will result in imposition of a reasonable
6 sentence that is sufficient but not greater than necessary
7 taking into consideration all of the factors set forth in
8 federal law.

9 A, the criminal fine of \$140,000,000 to be paid
10 within one week of the date of sentencing.

11 Do you understand that?

12 **MR. HOBART:** Yes.

13 **THE COURT:** B, mandatory special assessment
14 totaling \$400.

15 Do you understand that?

16 **MR. HOBART:** Yes.

17 **THE COURT:** C, criminal forfeiture in the amount of
18 \$10,000,000.

19 Do you understand that?

20 **MR. HOBART:** Yes, I do, Your Honor.

21 **THE COURT:** As far as restitution, I find that full
22 restitution has been made. The Federal Health Care Program
23 is part of the accompanying civil settlement of \$600,000,000
24 plus interest.

25 Do you understand that?

1 **MR. HOBART:** Yes, and agree, Your Honor.

2 **THE COURT:** And you agree with that?

3 **MR. HOBART:** Yes.

4 **THE COURT:** And with regard to the nonfederal
5 victims I find that the complication and prolongation of the
6 sentencing process that would result from an attempt to
7 fashion a proper restitution order outweighs the need for
8 such a restitution order because numerous unknown
9 individuals and insurance companies purchased or were
10 reimbursed for the drug products and tracing reimbursements
11 and determining apportionment of the payment would be
12 difficult, if not impossible.

13 Do you understand that?

14 **MR. HOBART:** Yes, Your Honor.

15 **THE COURT:** And do you have any objection to my
16 finding?

17 **MR. HOBART:** No, we agree with that finding, Your
18 Honor.

19 **THE COURT:** All right. Anything else that I should
20 take up now?

21 I don't think we have taken his plea yet so --

22 **MS. WINKLER:** No, you haven't.

23 **THE COURT:** Why don't you take the plea, Zita.

24 **THE CLERK:** Yes, Judge.

25 Mr. Hobart, as the appointed and designated

1 trustee, as to Count 1 of this Information charging you with
2 21 United States Code, Sections 331(a), 333(a)(2) and
3 351(a)(2)(B), charging you with interstate shipment of
4 adulterated drugs, how do you plead to Count 1?

5 **MR. HOBART:** As the authorized representative of SB
6 Pharmco Puerto Rico, Inc. we plead guilty.

7 **THE CLERK:** Thank you.

8 **THE COURT:** Any other comments anybody want to
9 make?

10 Let's have a basis in fact.

11 **MS. WINKLER:** Your Honor, the following statement
12 of facts is a general summary of some of the evidence that
13 the government would present at trial in this case with
14 regard to the charge presented against SB Pharmco.

15 SB Pharmco was a Puerto Rican corporation located
16 in Cidra, Puerto Rico. It owned and operated a
17 manufacturing facility there and it was an indirect
18 subsidiary of GlaxoSmithKline, a publicly traded company.

19 The evidence at trial would demonstrate that from
20 in or about March 2003 to October 2004, in Massachusetts and
21 elsewhere, SB Pharmco did, with intent to defraud and
22 mislead, cause to be introduced and delivered for
23 introduction into interstate commerce quantities of drugs,
24 to wit, Kytril, Bactroban, Paxil CR and Avandamet, that were
25 adulterated in that the methods used in and the controls

1 used for, drug manufacturing, processing, packing and
2 holding did not conform to and were not operated or
3 administered in conformity with current good manufacturing
4 practices.

5 The evidence would be that in 2001 Cidra was one of
6 the largest manufacturing facilities worldwide for GSK and
7 was a major supplier of pharmaceuticals to the U.S. market.

8 Cidra was responsible for a complex portfolio of
9 drug products, including pills, creams, ointments and
10 injectables. The plant was old. It had been built in the
11 1980s. And upon acquisition of the plant GSK realized it
12 posed risks because of certain deficiencies. Those risks
13 became more serious as time passed increasing the risk that
14 drugs might not be made in conformance with the cGMP, the
15 good manufacturing practices. And that meant the
16 pharmaceuticals were not made in a manner that guaranteed
17 they were of the strength, identity and purity and quality
18 that they purported to represent.

19 The evidence at trial would involve five areas of
20 concern. One is the drug Kytril which was an injectable
21 anti-nausea medication primarily used to treat patients
22 receiving chemotherapy or radiation or post-surgical
23 patients experiencing nausea.

24 As part of the merger GSK was required to have
25 Kytril divested to another drug manufacturer but GSK

1 continued to manufacture the product at the Cidra plant
2 until December 2003 when the acquiring entity got their
3 approvals from the FDA.

4 Kytril was made in the sterile suite at Cidra. An
5 internal audit by GSK found the sterile suite did not comply
6 with expectations, that a capital expenditure was necessary
7 to improve conditions or their operation should be
8 discontinued with a sense of urgency.

9 Evidence would have shown that in April or May 2003
10 SB Pharmco released Kytril, that it was deemed adulterated
11 because the manufacturing processes and lab testing were
12 insufficient to assure the quality and purity it was
13 represented to possess.

14 Bactroban is the second area. It was a topical
15 antibiotic used to treat skin infections. It was also made
16 in a sterile suite. The Quality Control Unit at Cidra
17 failed to properly review a batch in June 2001 that was
18 released to the market and not recalled until February 2002
19 during an FDA inspection of the plant. In that inspection
20 GSK identified one of the reasons that contamination could
21 be introduced into Bactroban was a practice of manually
22 scraping inside the tanks to get the last bit of product out
23 of the tank.

24 GSK assured the FDA that the practice would stop.
25 After a new site director was appointed to Cidra a year

1 later the practice was resumed as a cost-saving measure.

2 Thereafter, in or about October 2003 SB Pharmco
3 released a lot of Bactroban where there was potentially
4 objectionable microorganisms identified on equipment that
5 manufactured the lot and that lot was deemed adulterated
6 because the manufacturing processes and lab testing were
7 insufficient to assure that the Bactroban was of the quality
8 and purity that it was purported to represent.

9 A third area was Paxil CR, a controlled release
10 form of an antidepressant that was manufactured as a
11 bi-layer tablet, an active layer that had the therapeutic
12 part and a barrier layer that had the controlled release
13 formulation.

14 Shortly after the commercial production began at
15 Cidra, the tablet was observed to split between the layers,
16 something that was known as a critical defect.

17 In early 2003 in limited instances GSK performed a
18 test and determined that the cause of the splitting was a
19 result of too high a compression force on the active layer
20 which prevented the barrier layer from adhering properly.
21 The report recommended the installation of new load cells on
22 the presses so they could accurately read the compression
23 forces. Those load cells were not installed.

24 Until February 2004 SB Pharmco was using a visual
25 inspection to check for those splits before packaging. At

1 that time the company switched its statistical inspection of
2 the 12.5 and 25 milligram tablets which meant that only a
3 thousand tablets out of 1.5 to two million tablets that were
4 made in the batch were ever inspected. If no splits were
5 found in that 1,000 sample, the lot was released to the
6 market.

7 From February to September of 2004 during another
8 FDA inspection SB Pharmco used that statistical inspection
9 and it did not have adequate control over the compression
10 forces to assure that the tablets would not split.

11 Thus, during that time period lots of Paxil CR were
12 released that were deemed adulterated because the
13 manufacturing equipment was insufficient to control the
14 pressures and the process controls could not assure that the
15 Paxil CR released to market was of the strength, identity
16 and quality that it was supposed to represent.

17 The fourth area was Avandamet, a drug used to treat
18 diabetes and it consisted of a blend of two different
19 ingredients. Shortly after commercial production began GSK
20 found content uniformity problems in some batches of the
21 Avandamet. That means that the content was not as it was
22 supposed to be of the two different ingredients.

23 In October 2003 and again in November 2004 the FDA
24 found inadequate processes and corrective actions by SB
25 Pharmco to investigate and correct the content uniformity

1 problems with Avandamet.

2 Ultimately experts at GSK determined that the
3 humidity sensor in one of the machines was not properly
4 calibrated and a spacer or washer had been inserted in the
5 milling machine when it was installed.

6 Thus, between March 2003 and October 2004 certain
7 lots of Avandamet were released to market where the
8 manufacturing processes and lab testing procedures were
9 insufficient to assure the drug was of the strength,
10 identity and quality it was purported to possess.

11 Finally, product mix-ups were an issue at Cidra.
12 The line clearance on the packaging lines were insufficient
13 to prevent rogue tablets from getting into the wrong
14 packages. The site director who was in charge in 2003 and
15 2004 would collect those pills and instead of conducting
16 investigations to find out what happened put them in a
17 gowning hat in her office.

18 **THE COURT:** Put them in a what?

19 **MS. WINKLER:** In a gowning hat, a hat they wear to
20 protect from bacteria getting into the processes.

21 **THE COURT:** I see.

22 **MS. WINKLER:** Which meant there was a possibility
23 of the products being commingled into the wrong pill
24 bottles.

25 And for all these reasons and all as further set

1 forth in the information, the evidence at trial would show
2 that between March 2003 and October 2004, in Massachusetts
3 and elsewhere, SB Pharmco with intent to defraud and mislead
4 caused to be introduced and delivered for introduction into
5 interstate commerce quantities of drugs as earlier described
6 that were adulterated in violation of Title 21, U.S.C.,
7 Sections 331(a), 333(a)(2) and 351(a)(2)(B).

8 **THE COURT:** All right. Thank you.

9 Do you have anything you wanted to add?

10 **MR. HOBART:** No, Your Honor, just that SB, on
11 behalf of SB Pharmco Puerto Rico, Inc., the company agrees
12 that there is a sufficient basis in the evidence to support
13 the guilty plea.

14 **THE COURT:** All right. Thank you.

15 I am satisfied that the defendant understands the
16 nature of the accusation against it in this count, that it
17 understands the maximum consequences of its guilty plea,
18 that it has pleaded guilty voluntarily and that there is a
19 basis in fact for it having done so.

20 I am going to impose the sentence that I referred
21 to earlier, as follows:

22 A criminal fine of \$140,000,000 to be paid within
23 one week of the date of sentencing.

24 B, mandatory special assessment totaling \$400.

25 C, criminal forfeiture in the amount of

1 \$10,000,000.

2 And, D, I find that full restitution has been made
3 as part of the accompanying civil settlement of \$600,000,000
4 which is attached hereto as an exhibit.

5 Anything else that I should cover before we --

6 **MS. WINKLER:** Your Honor, I would just ask that
7 with regard to the restitution, the \$600,000,000 is full
8 restitution for the federal programs but for the nonfederal
9 programs your earlier finding that it would unduly
10 complicate and prolong the sentencing process --

11 **THE COURT:** I did say that. I will add that now,
12 just to make it clear.

13 With regard to the -- the \$600,000,000 was for the
14 federal restitution. With regard to the nonfederal victims,
15 I find that the complication and prolongation of the
16 sentencing process that would result in such an attempt to
17 fashion a proper restitution order outweighs the need for
18 such a restitution order because numerous unknown
19 individuals and insurance companies purchased or were
20 reimbursed for the drug products and tracing reimbursements
21 and determining apportionment of payment would be difficult,
22 if not impossible.

23 Is that satisfactory?

24 **MS. WINKLER:** Yes, Your Honor.

25 And one other thing.

1 **THE COURT:** Go ahead.

2 **MS. WINKLER:** There is a motion pending for order
3 of forfeiture that is assented to by the defendants. It
4 would be appreciated if you'd allow that.

5 **THE COURT:** I have it right here.

6 **THE CLERK:** Yes.

7 **THE COURT:** No objection to this motion?

8 **MR. HOBART:** No, Your Honor.

9 **THE COURT:** Okay. I am allowing it.

10 And I am signing the order as well.

11 Does that cover everything?

12 (Whereupon, the Court and the Clerk conferred.)

13 **THE COURT:** We are making one change which I think
14 you have to endorse here.

15 Zita will find the original.

16 (Pause in proceedings.)

17 **THE COURT:** That is the trouble with having the
18 judge read all that stuff, he might find something.

19 (Laughter.)

20 **THE COURT:** Just initial it, that will be
21 satisfactory to me.

22 **MS. WINKLER:** Okay.

23 (Pause in proceedings while counsel initialed the
24 document.)

25 **THE COURT:** Now, you have been sentenced and as one

1 who has been sentenced, you can appeal that sentence. You
2 have ten days to file a notice of appeal if it is your
3 intention to do so.

4 Do you understand that?

5 **MR. HOBART:** I do, Your Honor. And the company in
6 the plea agreement waived that right.

7 **THE COURT:** All right. I just want to make sure
8 you are well aware of it.

9 Anything else?

10 **MS. WINKLER:** No, Your Honor.

11 **THE COURT:** Anything else?

12 **MR. HOBART:** No, Your Honor.

13 **THE COURT:** All right. Thank you for your
14 cooperation. You are all dismissed.

15 **THE CLERK:** All rise for the Honorable Court.

16
17 (WHEREUPON, the proceedings were recessed at 2:45
18 p.m.)
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C E R T I F I C A T E

I, Carol Lynn Scott, Official Court Reporter for the United States District Court for the District of Massachusetts, do hereby certify that the foregoing pages are a true and accurate transcription of my shorthand notes taken in the aforementioned matter to the best of my skill and ability.

/S/CAROL LYNN SCOTT

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DATE: November 18, 2010